

### **Amendments to the Specification:**

Please delete previously submitted substitute FIG 12 (having FIGs. 12A- 12F thereon) and insert in its place original FIG. 12 (having FIGs. 12A-12D thereon).

Please delete the paragraphs beginning at page 2, line 28 and ending at page 3, line 24 and substitute therefor the following paragraphs:

~~FIG. 1 provides~~ FIGS. 1A-1D provide several views of ~~the fusion a~~ a substantially "D"-shaped cortical bone implant of this invention. FIG. 1E shows the detail of the inscribed feature of FIG. 1D.

~~FIG. 2 provides~~ FIGS. 2A and 2B provide side and end-on views, respectively of the core cutter and drill assembly. FIGS. 2C and 2D provide views and of the bone plug formed by cutting into the diaphysis of a long bone when such a core cutter and drill assembly is used.

FIG. 3 3A provides a view of broach as used according to this invention, ~~and~~ FIG. 3B provides an end-on view of an asymmetric canal formed by use of such a broach.

~~FIG. 4 provides~~ FIGS. 4A-4E provide several views of an apparatus for machining a profile on the exterior surface of ~~the~~ an implant of this invention.

FIG. 5 5A provides a top view of an apparatus for inscribing retention teeth in the upper surface, lower surface or both upper and lower surfaces of the implant. FIG. 5B is a side-view of a implant mounting device having a "D"-shaped cavity. FIGS. 5C-5E provide views of an alternate apparatus and method for fashioning the retention teeth in an implant.

~~FIG. 6 provides~~ FIGS. 6A-6C, 6D-6F and 6G-6I, respectively, provide several views and dimensions for three specific embodiments of the an implant of this invention.

~~FIG. 7A provides~~ FIG. 7 7B provides a side view of a stacked embodiment of the implant two implants of FIG. 7A of this invention shown in juxtaposition.

~~FIG. 8 8A provides several views~~ a view of an implant of this invention formed by juxtaposition of mirror image halves of the implant; FIGS. 8B and 8C shows the implants of the invention in bone stock. FIGS. 8D-8G show several views of as well as an embodiment useful for posterior lumbar intervertebral fusion procedures (PLIFs).

FIG. 9 provides a view of a stacked embodiment of the implant of this invention wherein the stacked constituents thereof are retained in registered relationship by press-fitting or otherwise bringing more than one implant into contact with each other and having a cancellous plug or other biocompatible material located in the central canal of each stacked implant, thereby acting as a retention pin.

~~FIG. 10 shows~~ FIGS. 10A and 10B show an alternate method for producing bone stock for making the implant of this invention of essentially unlimited height from the anterior margin of the tibia (FIG. 10B) or the linea aspera of the femur (FIG. 10A). FIG. 10C shows an end of a section of long bone.

FIG. 11 shows dimensions and further processing of the ~~implant of this invention produced according to the alternate method of bone of~~ FIG. 10 10C.

~~FIGS. 12-17 show final profiles for implants~~ FIGS. 12A-12D show several views of an implant produced according to the alternate method of FIGS. 10 and 11. ~~Fig. 12E show an embodiment of the implant of Fig. 12A formed from two stacked components.~~ ~~Fig. 12F show an embodiment of the implant of Fig. 12A formed from two components in juxtaposition.~~ FIG. 12A is a top view and the outer dotted profile provides a means for comparing the

external profile of the implant with the implant of FIG. 6. FIG. 12B is a side view; FIG. 12C is a detail view of the grooves which angle toward the posterior of the implant; and FIG. 12D is a sectional view through line A shown in FIG. 12A.

FIGS. 13A-13D correspond to the views of the implant of FIGS. 12A-12D, further containing a cancellous plug shown as a top view in FIG. 13E and as a side view in FIG. 13F.

FIGS. 14A-14D are views of an implant that correspond to the views in FIGS. 12A-12D but that has different dimensions as per Table I.

FIGS. 15A-15D correspond to the views of the implant of FIGS. 14A-14D, further containing a cancellous plug shown as a top view in FIG. 15E and as a side view in FIG. 15F.

FIGS. 16A-16D are views of an implant that correspond to the views in FIGS. 12A-12D but that has different dimensions as per Table I.

FIGS. 17A-17D correspond to the views of the implant of FIGS. 16A-16D, further containing a cancellous plug shown as a top view in FIG. 16E and as a side view in FIG. 16F.

Please delete the paragraph beginning at page 9, line 24 of the specification, and substitute therefor the following paragraph:

Referring now to ~~figure~~ FIG. 1A, there is shown a top view, as if viewed from the top of the spinal column, of a substantially "D"-shaped cortical bone implant 100. The implant has a wall thickness 101, a length 103, a width 102, and an internal canal 104, which fall within desired tolerances (see discussion below). The implant comprises four contiguous

walls, including a substantially straight rear wall 105, substantially straight side walls 106 and 107, and a preferably curved front wall 108. In ~~figure~~ FIG. 1B, there is shown a side view of the implant 100, revealing the height 109, of the implant. In addition, this view shows, in outline, the internal side walls 106' and 107' of the internal canal, 104. It also shows the top 110 and bottom 111 surfaces of the implant. In ~~figure~~ FIG. 1C, there is shown a top view of an embodiment of the implant 100 in which an external feature 120 has been inscribed onto the top 110 and bottom 111 surfaces of the implant. In addition, a "radius" or bevel 115 is shown on the two side and posterior edges of the implant. Figure FIG. 1D shows a side view of the implant 100 in which the inscribed feature 120 can clearly be seen in the top 110 and bottom 111 surfaces of the implant. In this view, it can be seen that the external feature 120 has the side profile of a set of teeth, all of which angle toward the anterior face 108 of the implant. An outline of the bevel 115 is also evident in this view, as is the rounded posterior edge 105. As can be seen, in this embodiment of the invention, the anterior edge 108 is maintained with a sharp edged. In ~~figure~~ FIG. 1E, there is shown a detail of one embodiment of the inscribed feature 120 on the portion of the implant indicated in ~~figure~~ FIG. 1D. In a preferred embodiment, the feature 120 defines a tooth-like structure, with teeth 121 separated from each other by concavities 122. An angle  $\theta$  defines the grade of the concavity as it ramps to the tooth. The tooth height 123, space between teeth 124, and aperture of the concavity 125 may all be defined by the manufacturer to optimize retention of the implant within the cervical spine after proper placement.

Please delete the paragraph beginning at page 15, line 9 of the specification, and substitute therefor the following paragraph:

In ~~figure~~, ~~figure~~ FIG. 5A, there is provided a top view of one side of one embodiment of blades 502 for use in a broach assembly 500 for inscribing teeth into the top 110, bottom 111 or both surfaces of the implant. In outline, there is shown a lock-down handle 501 for

clamping the assembly of blades 502 to a base 503. By bringing a mirror image jaw into register with the depicted broach, a space is formed between the opposing teeth 502 at a distance sufficient to accommodate passage of the implant therebetween, provided that the teeth abrade recesses into the top and bottom surfaces of the implant 100. To ensure proper engagement of the blades 502 and the implant 100, there is provided a non-cutting surface 506 for contacting the implant 100 as it is introduced into the broach assembly 500. The non-cutting surface 506 acts as a type of micrometer, forcing the cutting surfaces of the teeth 502 sufficiently apart to properly engage the implant as it passes through the broach assembly 500. In ~~figure~~ FIG. 5B, there is provided a side view of an implant mounting device 504 having a "D"-shaped cavity 505 into which a "D"-shaped implant may be fitted for passage through the opposing jaws of the broaching jaw apparatus 500. The resultant implant has the profile shown in ~~figures~~ FIGS. 1C-1E.

Please delete the paragraph beginning at page 18, line 10 of the specification, and substitute therefor the following paragraph:

In addition to use for cervical Smith-Robinson type fusion, implants comprising each element, 801A or 801B alone, modifications and variations thereof, optionally in combination with another vertebral fusion implant, may be implanted, for example, to assist in induction of posterior lumbar intervertebral fusion (PLIF). In such a case, a device 810, such as that shown in ~~figures~~ FIGS. 8D-8G is machined from bone stock as shown in ~~figures~~ FIGS. 8B, 8C or another appropriate bone stock, and is inserted, according to methods known in the art for insertion of PLIF implants. Preferably, the device as used for PLIF applications has the following dimensions similar to the following, see ~~side~~ top view ~~figure~~ FIG. 8D: a width 811 of approximately 7 to 12 mm, and preferably about 9.4 to about 10 mm; a top dimension 812 of about 4 to 5 mm; a bottom dimension 813 of about 4-6 mm and preferably about 5 mm; a flat surface of 814 of about 4-7 mm, and preferably about 5.5 mm; a width 815 of about 5-7 mm and preferably about 5 mm; a curvature that defines an angle 816 of between about 60 and 75 degrees, and preferably about 67 degrees.

See figure FIG. 8E, rear view: a length L of about 20 to 26 mm; a height H of between about 7.5 and 14.5 mm; preferably, heights of about 8, 10, 12, and 14 mm are produced with lengths of about 20 and 26 mm; desirably, the side faces 817 are machined to display a rough, ridged or grooved surface so that when the anterior end 818 of the PLIF implant is properly seated in place, ridges directed to the posterior end 819 of the PLIF implant prevent backing out of the implant. A detail of one embodiment of such a ridged surface is shown in figure FIG. 8F, wherein the following dimensions are preferred: an angle 820 for each tooth of between about 30 and 40 degrees, preferably about 35 degrees; a distance between tooth crests 821 of about 1-2 mm, preferably about 1.5 mm; a tooth crest width 822 of about 0.1 to about 0.2 mm, preferably about 0.125 mm; and a tooth height 823 of between about 0.1 to about 1 mm and preferably about 0.5 mm; returning to figure FIG. 8E, the implant preferably has an anterior end width 824 of about 7-13 mm, preferably about 9-13 mm, with a taper angle 825 from the height H of about 30 to 40 degrees, preferably about 35 degrees; an instrument attachment means, 826, such as a tapped instrument attachment hole, is provided in the posterior face of the PLIF implant; this feature is best seen from the posterior view of FIG. 8G, which shows: an instrument attachment hole 826 having a diameter of about 1.5 to about 2.5 mm, preferably about 2 mm, and a depth of about 4-5 mm, preferably about 4.5 mm; an edge to center of the instrument attachment hole dimension 827 is carefully defined to match dimensions of any implant insertion device used in combination with this embodiment of the PLIF implant; a center of the instrument attachment hole to edge dimension 828 is about 4-6 mm, preferably about 5 mm, with a ridge 829 of about 1 mm running along three edges of the posterior face of the implant. In displaying the section A-A from figure FIG. 8D in figure FIG. 8E, a slight air gap 830 is shown as the section would exit bone on the concave surface of the implant and then reenter bone.

Please delete the paragraph beginning at page 19, line 20 of the specification, and substitute therefor the following paragraph:

In an analogous but alternate method for production of the cervical implant, unitary implants may be produced by appropriately sectioning and machining the anterior margin of the tibia or linea aspera of the femur. Thus, as shown in ~~figure~~ FIG. 10A, a left femur 1000 (posterior aspect), or in ~~figure~~ FIG. 10B, a left tibia 1001 (anterior aspect), is sectioned at 1004 and 1005 to remove the head, neck and greater trochanter 1002 and internal and internal condyles 1006 of the femur, or tubercle and tuberosity 1003 malleolus 1007 of the tibia. The result from such sectioning is the production of a shaft, or diaphysis, of the femur 1008 or tibia 1009. Further processing according to this aspect of the invention involves the ~~line-asper~~ linea aspera 1010 of the femur or the anterior margin of the tibia 1011, as shown in ~~figure~~ FIG. 10C. Whether produced from the femur or tibia, a diaphysial shaft 1012, extending as shown at 1016 to a length permitted by the length of the shaft produced by the sectioning at 1004/1005. The shaft comprises the natural intramedullary canal 1013. The thus produced shaft is then further sectioned in a plane shown at 1014 to produce a shaft of bone removed from the natural intramedullary canal 1013 having a cylindrical but somewhat triangular external shape. Into this shaft may be drilled a cannulation 1015, as shown in ~~figure~~ FIG. 11.

Please delete the paragraph beginning at page 21, line 1 and substitute therefor the following paragraph:

~~Figure-13~~ FIG. 13A shows a device similar to that of ~~figure-12~~ FIG. 12A, with a cancellous plug inserted therein. ~~Figure~~ FIG. 14 shows a device having a width W1 of about 14 mm and a height H1 of between about 5 mm and about 14 mm. ~~Figure-15~~ FIG. 15A shows a device similar to that of ~~figure-14~~ FIG. 14A with a cancellous plug inserted therein. ~~Figure~~ FIG. 16 shows a device having a width W1 of about 14 mm, a width W2 of about 14 mm, and a height of between about 5 mm and 11 mm. ~~Figure-17~~ FIG. 17A shows a device

similar to that of ~~figure~~ FIG. 16A having a cancellous plug inserted therein. Table I below summarizes the various features and provides examples of specific dimensions for various embodiments of the implant of this invention shown in ~~figures~~ FIGS. 12-17: